56. An isolated polypeptide comprising a complement binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig.1 (SEQ ID NO: 2).

REMARKS

Pending Claims

Claims 49-56 are under examination in the case. Claims 49-56 stand rejected for double patenting. Claims 49-51 and 54-56 are rejected under prior art. Applicants respectfully request reconsideration of the outstanding objections and rejections for the reasons that follow.

Terminal Disclaimer

The Examiner has indicated that the terminal disclaimer provided in the prior response did not reach the Examiner intact; some of the pages were missing. Accompanying this amendment please find a copy of the terminal disclaimer including p 1-3 and executed by Patricia Anderson Cotton and Janet E. Hasak containing the appropriate signatures is attached. Removal of this rejection is requested. Also accompanying this amendment, please find 1 page of certificate created by Yvonne Carter.

Prior Art Rejection

The Examiner has maintained the rejection of claims 49-51 and 54-56 as anticipated by Woodruff et.al. The Examiner asserts that the reference discloses the human lymphocyte homing receptor, and that the disclosed receptor inherently has the same structure and sequence as the claimed polypeptide, because "the receptor was identified using the same technique as the mouse and rat and is isolated from the T-cells as are all the other LHRs." (Office Action, Paper No. 14, page 3). Applicants respectfully traverse this rejection.

According to MPEP Section 2112, to rely on a theory of inherency for finding anticipation, the Examiner must provide a basis in fact or technical reasoning to support a determination that the inherent characteristic *necessarily* flows from the teachings of the applied prior art. No such necessary flow is present here.

The cited reference fails to disclose or teach any structure, sequence, pattern, or function to correlate the claimed molecules and those disclosed in the reference. The examiner suggests the molecules disclosed and claimed inherently have the same sequence "because the receptor was identified using the same technique as the mouse and rat and is isolated from the T-cells as are all other LHRs".

Contrary to the Examiner's assertion, the reference fails to identify receptor "using the same techniques" as described in the reference. In the instant invention, Mel 14, a *monoclonal* antibody directed against a suggested murine lymphocyte surface protein, was used to affinity purify the murine protein. An oligonucleotide probe was then designed from N-terminal amino acid sequence information obtained from the monoclonal antibody-purified murine protein, and the probe was used to isolate a clone encoding the human protein from a cDNA library.

In contrast, the Woodruff reference teaches affinity purification of the human protein using a *polyclonal* antibody. Purification using a polyclonal antibody can result in a myriad of different isolated polypeptides because the polyclonal antibody recognizes a diverse mixture of different epitopes. In addition, the mixed population of human polypeptides that is obtained by polyclonal antibody purification in the Woodruff method would not provide useful amino acid sequence information for the design of oligonucleotide probes. Since the practitioner was unable to use the Woodruff protein preparation to obtain a human cDNA clone encoding the human protein and could not replicate the work done by the present inventors. Moreover, because the methods used in the Woodruff reference also produced a polypeptide mixture having functional distinctions when compared to the polypeptide of the invention, as disussed in the prior response, the proteins cannot be the same.

Accordingly, the claimed invention cannot be inherent in the polypeptides disclosed in the specification. "The fact that a certain thing may result from a given set of circumstances is not sufficient [to find inherency]. (Mehl/Biophile Int'l Corp. v. Milgraum 192 F.3d 1362.

The invention is further distinguished from the cited reference by the specific recitation of structure in the claims. No structure or functional relationship is described in the cited

reference that would suggest that the cited polypeptide is the same protein as in the instant claims. Furthermore, the claims call for a specific polypeptide defined by sequence and structural elements not disclosed or inherent in the reference.

Conclusion

A complete terminal disclaimer has been provided to overcome the Examiner's double patenting rejection of claims 49-56; claims 52 and 53 have been amended to independent format. Because these claims are not rejected under prior art, they are now in condition for allowance.

Claims 49-51 and 54-56 have been distinguished over the cited reference and are believed to be in condition for allowance.

The Examiner is invited to telephone the undersigned attorney to clarify these amendments and remarks, or to otherwise speed prosecution of this case.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: July 30, 2001

Katherine M. Kowalchyk

Katherine M. Kowalchyk
Reg. No. 36,848

VERSION WITH MARKINGS TO SHOW CHANGES MADE

49. An isolated polypeptide encoded by a DNA able to hybridize under stringent conditions to the complement of a DNA sequence encoding the carbohydrate binding domain, the epidermal growth factor domain, or a complement binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig. 1 (SEQ ID NO: 2).

50. The polypeptide of claim 49, wherein the stringent conditions are overnight incubation at 42^0C in a solution comprising: 20% formaldehyde, 5XSSC (150 mM NaCl, 15mM trisodium citrate), 15 mM sodium phosphate (pH7.6), 5X Denhardt's solution, 10% dextran sulfate, and 20μg/ml denatured, sheared salmon sperm DNA.

51. The polypeptide of cliam 49 encoded by a DNA able to hybridize under stringent conditions to the complement of a DNA encoding the carbohydrate binding domain of the LHR amino acid sequence shown in Fig. 1 (SEQ ID NO: 1).

52. (Amended) [The polypeptide of claim 49] An isolated polypeptide encoded by a DNA able to hybridize under stringent conditions to the complement of a DNA sequence encoding the carbohydrate binding domain, the epidermal growth factor domain, or a complement binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig. 1 (SEQ ID NO: 2), wherein the polypeptide [which] is devoid of a functional transmembrane domain.

53. (Amended) [The polypeptide of claim 49] An isolated polypeptide encoded by a DNA able to hybridize under stringent conditions to the complement of a DNA sequence encoding the carbohydrate binding domain, the epidermal growth factor domain, or a complement binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig. 1 (SEQ ID NO: 2), wherein the polypeptide [which] is devoid of a functional cytoplasmic domain.

54. An isolated polypeptide comprising the carbohydrate binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig.1 (SEQ ID NO: 2).

55. An isolated polypeptide comprising the epidermal growth factor domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig.1 (SEQ ID NO: 2).

56. An isolated polypeptide comprising a complement binding domain of the leukocyte homing receptor (LHR) amino acid sequence shown in Fig.1 (SEQ ID NO: 2).